REMARKS

A Declaration of Jan F. Baumgardner, M.D. including two Exhibits is enclosed.

As required by the Examiner, claims 2-23 and 25 - 52 have been withdrawn. The applicant is entitled to have these claims reinstated if a generic claim is allowed, and requests that this be done. If a formal petition requesting reinstatement has not been filed by the time of allowance or appeal, then please consider this to be such a petition and an authorization for the Commissioner to charge the appropriate fee to deposit account No. 50-1848.

Previously Filed Response

A Final Office Action was mailed in the application on July 28, 2003 (hereinafter, "the Final Office Action"). A response to that final office action was faxed to the USPTO on October 28, 2003 (hereinafter, "the Response to Final Office Action'). A copy of that response is enclosed. An Advisory Action was mailed on December 12, 2003 (hereinafter, "the Advisory Action"). The Advisory Action indicated the Amendment in the Response to Final Office Action would not be entered. Please enter the Response to Final Office Action prior to entering this Supplemental Response.

Claim Rejections – 35 USC §112, second paragraph

In the Final Office Action, claims 1, 24, and 53 – 64 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. The Advisory Action indicated that the Response to Final Office Action overcame that rejection. Therefore this rejection is considered to be overcome.

Claim Rejections – 35 USC §112, first paragraph

In the Office Action dated July 28, 2003, the Examiner rejected claims 24 and 59 – 64 under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most merely connected, to make and/or use the invention. This rejection is respectfully traversed.

The Examiner cited *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Circ. 1988) in support of this contention. With respect to each of the factors mentioned by

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the Examiner, we hereby incorporate the arguments of the Response to Final Office Action.

However, we respectfully submit that a further discussion of the factors in *Wands* will not advance the prosecution of this application, and is in fact a diversion from the real issues herein. First of all, the Examiner states that *Wands* "is cited to show the factors which are relied on to determine if and application is enabled for what is claimed." Wands does not say this. Wands says that the factors are to be used to determine if *undue experimentation* is required to enable one skilled in the art to practice the claimed invention. 35 CFR 112, first paragraph does not mention either the factors in *Wands*, nor undue experimentation. Thus, a discussion of these factors is two levels removed from the statute. Further, in *Wands*, the court held that the claims were patentable. Thus, *Wands* does not give any real assistance in determining why claims may not be patentable. Therefore, we would like to return the discussion to the language of the statute.

The statute only requires that the specification enable a person skilled in the art to make and use the invention. The courts have interpreted this to mean that one skilled in the art can not only make the claimed invention, but that the invention as disclosed in the specification works. The Examiner has admitted that the specification enables one skilled in the art to make many compositions that meet the claims. See the Final Office Action, page 8, lines 13 – 17. However, the Examiner insists that... "one skilled in the art would not come to the conclusion that the compositions indeed have efficacy...". Thus, efficacy appears to be the real issue.

The attached Declaration of Jan F. Baumgardner, and the Exhibit B attached to the Declaration, which Exhibit B is a draft Executive Summary and Final Report on a clinical study on a product made according to claims 1 and 24, show that one skilled in the art not only would conclude the compositions have efficacy, but that they indeed are effective. We think the Declaration and Report speak for themselves, so we will not rehash them here.

For the above reasons, claims 1, 24, and 53 – 64 are believed to be patentable, and their reconsideration and allowance are respectfully requested. Also requested are reconsideration and allowance under 37 CFR 1.141 of previously withdrawn species claims 2 – 23, and 25 – 52. The undersigned attorney requests the Examiner to telephone the

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undersigned if a conversation could expedite prosecution. No additional fee is seen to be required, but if a fee is required, please charge it to Deposit Account No. 50-1848.

Respectfully submitted,
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